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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,950	03/27/2001	Paul M. Guyre	DC-0153	4097

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EXAMINER
JAMROZ, MARGARET E

ART UNIT	PAPER NUMBER
1644	7

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/817,950	GUYRE ET AL.	
	Examiner	Art Unit	
	Margaret E Jamroz	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *5-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-10 are pending.

2. Applicant's election with traverse of Group I (claims 1-4) in Paper No. 6 is acknowledged.

The traversal is on the ground(s) that all claims relate to the presence of CD163 in a biological sample and searching would not require a significant burden. This is not found persuasive because groups I-III are classified in different groups and are recognized divergent subject matter. Specifically, the methods of detecting in Group I (claims 1-4) recite an antibody against CD163. The composition in Group II (claims 5-6) is CD163, and the compounds recited in group I are antibodies directed against CD163, therefore, groups I and II are not even related as a product and process of using; in addition, they are classified differently which would require a different search. The methods of Group III (claims 7-10) require a composition comprising CD163, not antibodies directed against CD163, therefore, the restriction between Groups I and III is proper. The methods and compositions recited, therefore, are distinct and independent, and searches of all groups would place an undue burden upon the examiner due to the distinct and separate classification of each group.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-10 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to non-elected inventions.

Claims 1-4 are under consideration in the instant application.

3. Applicant's IDS, filed 7/23/2001 (Paper No. 3), is acknowledged, however, the references with the page numbers crossed out were considered only in regard to the Abstract. Applicant is invited to produce such documents.

4. The disclosure is objected to because of the following informalities: page 13, line 3 refers to Table I, however, applicant has not included Table I in the instant specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

(A) Antibodies MAC2-158, MAC2-48, and RM3/1 recited in claim 2 are essential to the claimed invention. They must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the antibodies, and it is not apparent if the antibodies are readily available to the public.

If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the antibodies have been deposited under the Budapest Treaty and that the antibodies will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made

herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit, 5 years after the last request for a sample, or for the enforceable life of the patent whichever is longer. See 37 CFR 1.806.

If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the antibodies described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

(B) The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112).

The attempt to incorporate subject matter into this application by reference to Hogger et al. (*Pharm. Res.* 1998; 15: 296-302) for the monoclonal antibody RM3/1 on page 4, line 14 of the specification is improper because an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set in the MPEP 608.01(p).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coligan et al. (Current Protocols in Immunology, Greene Publishing Associates and Wiley-Interscience, New York, 1991; pages

2.1.1-2.1.3, 2.1.9-2.1.11, and 2.1.17-2.1.22) in view of U.S. Patent 5,077,216, and Zwadlo et al (IDS Reference BA) and the known fact disclosed in the specification on page 4, paragraph 1.

Coligan et al. teach an Antibody-Sandwich ELISA to detect soluble antigens, which is the most useful of the immunosorbent assays for detecting antigen because it is very sensitive (see page 2.1.9 in particular). Plates are coated with a specific capture antibody, test samples added, and soluble antigens are detected with another antibody. A developing reagent is added to detect antibody/antigen complexes (see page 2.1.9 in particular). Coligan et al. teach that ELISAs are useful for screening biological fluids (e.g. from plasma) for antigen content (see page 2.1.20, left column in particular).

Coligan et al. do not teach antibodies directed against CD163, samples from human plasma, the monoclonal antibodies MAC2-158, MAC2-48, RM3/1, or a method of monitoring the course of an inflammatory condition or inflammatory process in biological samples via the method of claim 1.

The '216 patent teaches a method of detecting a p155 human mononuclear phagocyte-specific antigen using the monoclonal antibodies **MAC2-158** and **MAC2-48** (see columns 1, 7, 12, and the claims in particular). The monocytes detected were obtained from human plasma (see column 5, paragraphs 1-2 in particular).

Zwadlo et al. teach a method of detecting a monocyte surface antigen with a monoclonal antibody (**RM3/1**) wherein the monocytes were obtained from freshly isolated peripheral blood monocytes (see the Abstract, the Materials and Methods, and Figure 2 in particular). Zwaldo et al. further teach a method of monitoring the course of an inflammatory condition/process comprising detecting RM3/1 in a biological sample. RM3/1 was found in varying amounts in acute inflammatory sites depending on the stage of inflammation and that RM3/1 macrophages "increase during the healing phase and decrease during onset of inflammation" (e.g. gingivitis; see page 303, left column in particular). Further, many RM3/1 positive macrophages were observed during chronic inflammation (e.g. rheumatoid arthritis; see page 303, right column in particular).

The specification on page 4, paragraph 1, discloses the known fact that the p155 antigen, RM3/1, and CD163 are the same protein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the antibodies taught by the '216 patent as capture antibodies and the antibodies taught by Zwaldo et al. as the detection antibody in the ELISA assay taught by Coligan et al. to have a method for detecting the presence of CD163 in a biological sample comprising contacting the sample with a CD163 capture antibody to form a CD163 antibody complex and contacting said complex with a detection antibody so that the levels of CD163 in the sample are detected, and to use the method as discussed herein to have a method for monitoring the course of an inflammatory condition or inflammatory comprising detecting the presence of CD163 in biological samples as taught by Zwaldo.

One of ordinary skill in the art would have been motivated to substitute the antibodies taught by the '216 patent and Zwaldo et al. in the ELISA taught by Coligan et al. to detect and monitor the presence of CD163 in a biological sample, such as human plasma, during an inflammatory condition/process Antibody-Sandwich ELISA to detect soluble antigens, which is the most useful of the immunosorbent assays for detecting antigen because it is very sensitive and ELISAs are useful for screening biological fluids (e.g. from plasma) for antigen content as taught by Coligan et al. and monitoring the course of an inflammatory condition by detecting CD163 (i.e. RM3/1 antigen) such as rheumatoid arthritis is important as taught by Zwaldo et al.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this

application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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February 22, 2002

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